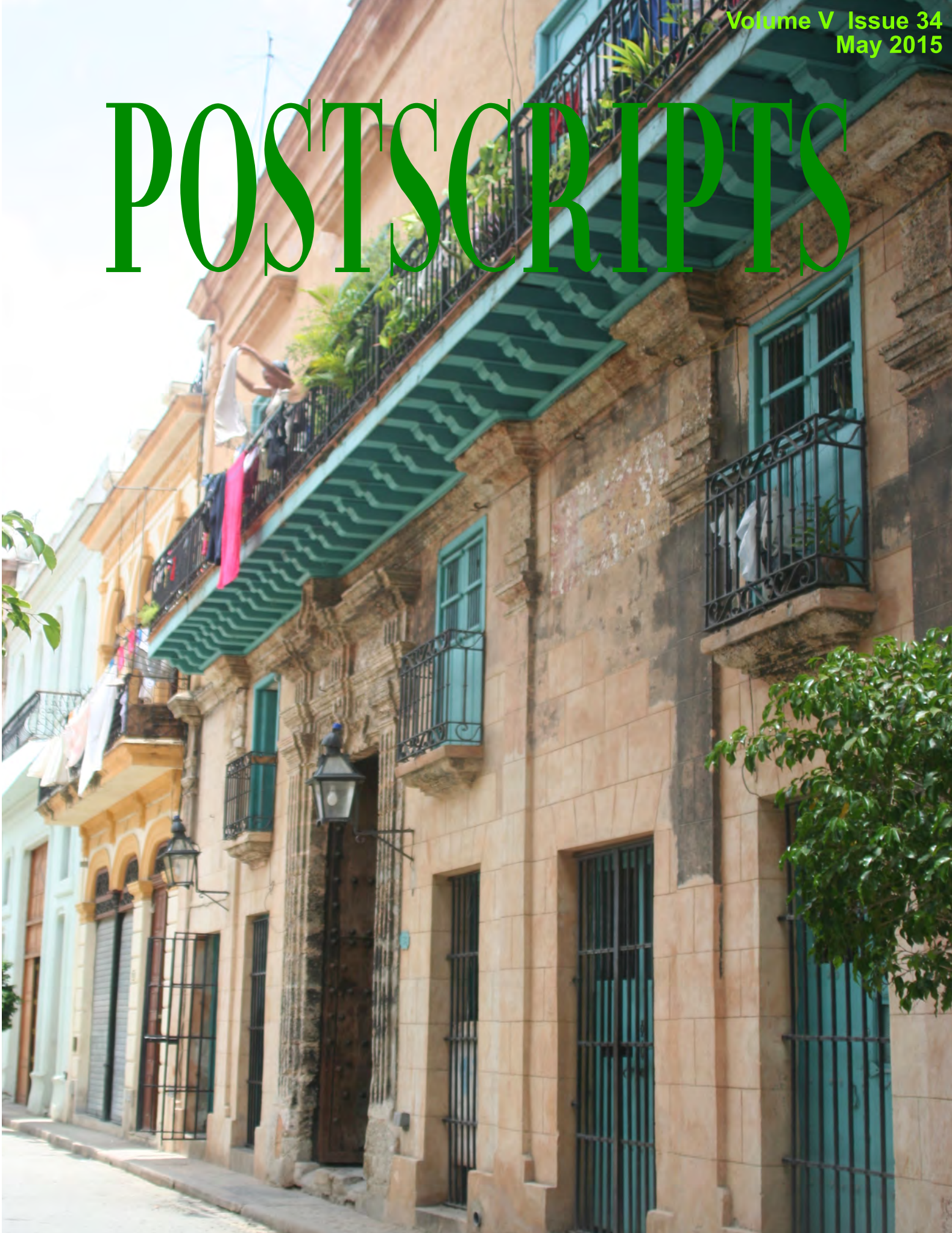
Volume V Issue 34
May 2015

POSTSCRIPTS



Official publication of the American Medical Writers Association Pacific Southwest chapter

Postscripts
May 2015
AMWA Pacific Southwest Chapter



POSTSCRIPTS

AIMS AND SCOPE
Postscripts magazine is the official publication of the Pacific Southwest chapter of the American Medical Writers Association (AMWA). It publishes news, notices and authoritative articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical and regulatory writing, scientific writing, publication planning, social media, current regulations, ethical issues, and good writing techniques.

MISSION STATEMENT
The mission of *Postscripts* is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, *Postscripts* publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; and, book and journal summaries. Additionally, to promote career and networking needs of the members, *Postscripts* includes news and event notices covering Chapter activities.

SUBSCRIPTION: *Postscripts* is published monthly except in January and July. The magazine is available as open access publication and is currently distributed online only.

INSTRUCTION FOR CONTRIBUTORS: We consider articles on any topic of interest to medical writers and communicators. It is helpful to look at the past December issues for year end table of contents, and browse past issues for style and type of articles published. We welcome contributions from AMWA members and non-members alike. Please contact editor.

ADVERTISING: *Postscripts* is an advertising-free magazine. However, articles describing products and services relevant to medical writers may be considered or solicited. As a service to our members, they may submit advertisements for their services or products for free. Please contact editor.

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Banner Photo Art by Chip Reuben, www.photoartwindows.com / Red phone booth. By Petr Kratochvil, publicdomainpictures.net

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From the President's Desk

"All things seem possible in May."
- Edwin Way Teale

Possible things have happened already in May…we held our first one-day Pacific Southwest chapter conference. Be sure to read next month's newsmagazine to learn about the educational, networking and fun Cinco de Mayo celebrations we experienced in Old Town San Diego!

Now that we are into May, "may" I welcome new members to our chapter. We met some of you at the chapter conference and we hope to meet the rest of you soon.

"May" I thank our long-time contributor Amanda Fisher for her column dedicated to recent news from the FDA. This is Amanda's last column for us so we thank her for all of her contributions over the years. We have great articles in this newsmagazine: two articles about open access by Ajay Malik and Dikran Toroser, a reprint of the 1994 article by Lanie Adamson, "A Tale of Two Printers", Rebecca Andersen's lament about the extinction of "pharmaceutical swag", and Sharyn Batey's summary of job opening in the area.

"May" we ask for our members to contribute to our chapter by writing some of the sections in our newsmagazine. We are looking for reporters to cover FDA, Safety/Pharmacovigilance and EMA news and announcements. We could also use help with covering news from the publication world, and summarizing hot topics being discussed in AMWA, ISMPP and other LinkedIn forums. The time commitment is minimal and our previous reporters would help train on how to obtain relevent information and write the articles. If you are interested, please contact Ajay at ajay@amwa-pacsw.org. Writing an article is a wonderful way to contribute to our chapter and get an online writing credit…it's a win-win!

"May" we tell you about our great chapter event about ophthalmology and medical writer by Denise Sturrock as reviewed by Clarice Chen and the fun networking events held in Arizona and La Jolla this past month. We also have a review of the recent AMWA Board meeting. Please look through the newsmagazine for more details.

We have other events that we are planning in the next few months (medical device, PowerPoint slides, experience writing a book, etc) and the Medical Writer's Toolbox Decoded session on September 19th (please visit our website, www.amwa pacsw.org, for more details). We could always plan more events so if you have a suggestion for topics or speakers, or would like to speak, please feel free to contact me (president@amwa-pacsw.org).

Enjoy the month of May with Mother's Day, and we hope to see you soon!

Donna

Donna Simcoe, MS, MS, MBA, CMPP
President, AMWA Pacific Southwest Chapter

Background image by Sandrinja via morguefiles. Image URL: http://mrg.bz/qe6UMN

AMWA Pacific Southwest chapter warmly welcomes our new members

Steven Hasal – Lake Forest

Irina ianculescu – Pasadena

Jacqueline Sayyah – Los Angeles

Ed Fontanilla – San Diego

Clarice Chen – Anaheim

Julian Kaye – La Jolla

Lamia Merabet – San Diego

Sean Sauber – Carlsbad

List courtesy of Gail Flores, PhD, AMWA Pacific Southwest chapter membership coordinator.

Beach By JessicaCooper1231 (www.morguefile.com/creative/JessicaCooper1231). Image URL: http://mrg.bz/U0Q6uA

EDITOR'S desk:

Open Access and ArXiv: Setting the Research Data Free



Eleven years ago, on January 22, 1994, a group of AMWA Pacific Southwest chapter members visited 2 state-of-the-art printing presses in Irvine county, Southern California. In the words of Lanie Adamson, the president of the chapter at that time, *the publishing industry was in the midst of a revolution*.[1] There was tremendous excitement in the air. The direct-to-press was a new breakthrough in the publishing world: "The file goes from the Macintosh or Windows to the printing press, with no negatives or printing plates needed, " wrote Lanie Adamson in the announcement for the printing press tour.[1]

While printing technologies have continued to evolve along with digital (computers) and now mobile technologies, in the world of scholarly publishing, they have only partly addressed a critical issue relevant to medical libraries' budget—the cost of journal subscriptions. The subscription cost of several for-profit journals have continued to climb to unaffordable levels, denying accessibility to published research to all but a few who can afford.

The Change is Coming

The pendulum has started swinging the other way, and we are now in the midst of a second revolution that will truly "set the words free". In this issue of *Postscripts*, Dikran Toroser describes the history and development of Open Access in scholarly publishing. Open Access publishing is truly a game changer

But, can pendulum *really* swing too far to the left? As Dikran points out, it can! One ugly side of Open Access publishing is a free-for-all environment where too many journals with little editorial oversight have entered the business of scholarly publishing. They have earned the nickname, "Predatory Journals." There is even a Wikipedia entry[2] on this topic complete with a link to Beall's list of predatory open access publishers and journals.

The ArXiv Model of Publishing

Faced with a less than perfect open access model of publishing where authors bear upfront cost to get their research published, a skeptic might say: Why pay at all for open access, why not just publish, even self-publish. As you might have guessed, there are initiatives in this direction, too. Dikran mentions the ArXiv preprint server (arxiv.org). Sharing research data and results via ArXiv (without going through peer-review) has been a standard practice in the physical sciences for years. The biologists are slow to catch up, as usual.

A few years back (in 1997), Nature Publishing Group (NPG) also got into the fray establishing *Nature Precedings* (precedings.nature.com). All submissions made to *Nature Precedings* have a citable DOI address. However, after 5 years, citing business reasons, NPG closed *Nature Precedings*.[3] But the concept of preprint publishing and sharing of research in biomedical sciences is only going the way of Main Street: In 2013, Cold Spring Harbor Laboratory Press in New York, launched bioRXiv preprint service (biorxiv.org/) and since then, there has been a steady uptake by biomedical scientists.

Although the alternate means of sharing research via preprint servers compared to traditional or open access e-journals are still in infancy, they serve the authors by avoiding the upfront cost and potential shame/stigma if peer review process is discovered to be questionable or fake. Acceptence of ArXiv model of publishing as citable sources by wider biomedical community would also save the taxpayers (funding agencies) a bundle in fees paid for open access.

In the AMWA LinkedIn discussion group, recently, Brain Bass, past president of AMWA, shared a news about retraction of several manuscripts by BioMedCentral editors for questionable (fake) peer-reviews. The ArXiv model of sharing data would have avoided such a heartache for authors, as citation and repetition of data by others would be the key for validation of published findings. *But, then we*

1. See Backpage for notice, and next page for Lanie's report
2. http://en.wikipedia.org/wiki/Predatory_open_access_publishing
3. Callaway E. Preprints come to life. Nature News. Nov 12, 2013. http://www.nature.com/news/preprints-come-to-life-1.14140

PICTURE: Seattle Daily Times news editor quarters - 1900. Via Wikipedia (http://en.wikipedia.org/wiki/Editing#mediaviewer/File:Seattle_Daily_Times_news_editor_quarters_-_1900.jpg)

would have missed dissecting a scandal on the AMWA LinkedIn group!!!

The medical writers who work with publications and expect to have their names in author bylines or acknowledgement section are well advised to avoid the ugly side of open access publishing, as our reputation depends on where our name appears in scholarly publishing and not testimonials. A good place to start is to be aware of Beall's list of predatory publishers and journals.

Open Access is here to stay. So much so that at the ISMPP Annual meeting in Virginia last month, Open Access was among one of the vigorously discussed topics. (Look for a meeting report on this conference in the next issue.)

The publication landscape is changing. . . Are you ready for it?

— Ajay K Malik, PhD

Postscripts Feb 1994

A TALE OF TWO PRINTERS

Phoenix Press and **Digital Quickcolor**, two printing companies in Irvine, opened their facilities for a tour for AMWA members on January 22. Both companies provide electronic prepress services and 4-color printing. They differ in technology and in the types of printing they produce.

Phoenix Press does layout, design, color separations, stripping, printing, binding, and order fulfillment. Their presses can run up to six colors: the four standard colors, two of any of the PMS (Pantone Matching System) colors, plus spot or full varnishing. PMS inks are used to generate a precise, consistent color, such as a corporate color for a company logo.

Digital Quickcolor, the research and development arm of Sir Speedy, specializes in 4-color, quick turnaround using a modified printing press networked to a computer—not unlike having your computer hooked up to a 16,000 pound laser printer.

Both companies use computer technology, starting with page layout done either in-house or provided on a disk or cartridge by the customer.

At **Phoenix Press**, the page layout file is sent to a device, called a Linotronic®, that generates one negative apiece for each color to be printed. The negatives are placed on light-sensitive printing plates and the image is burned onto the plate. The plates are then mounted on a printing press.

The number of colors depends on the type of press. One press can run six colors on one side of a page at one pass, or a combination of colors front and back simultaneously in a process called perfecting. With the perfecting press, three colors might be used per side, or four on one side and two on the other.

Digital Quickcolor uses waterless ink technology with electro-erosion. The page layout (eg PageMaker®) file is sent to a file server and then to the computer-driven printing press. The computer directs an electronic device on the press as it burns the color image onto each of the printing plates mounted on the four imaging units. A maximum of four colors can be run, either four on one side or up to two colors per side in the perfecting process.

Color is produced in a similar fashion with both technologies. A continuous tone photograph, for example, is separated electronically into tiny dots of the four basic colors: cyan (blue-green), magenta (red-blue), yellow, and black (called CMYK in the industry). Nearly every color can be generated from the dot patterns of these four basic colors. (PMS colors do not originate from dot patterns.)

In the technology used by **Phoenix Press**, a laser burns thousands of tiny holes onto a negative. In the electro-erosion technology used by **Digital Quickcolor**, these spots are generated by an electronic spark that produces a tiny spatter instead of the crisp clean dot of the Linotronic® laser beam. Greater precision is forthcoming with the next evolution of this technology, called Pearl.

Both companies emphasized the need for a close working relationship with the printer from the genesis of the project and both provided examples of printing jobs gone awry. Sometimes what you see on the screen is not what you get on the press. The color blue may have the perfect hue and density as seen with the light shining through it on the computer monitor, but be muddy when it is printed. A photo scanned on an office scanner and placed into the page layout may lack detail and color. An assessment of the type of printing desired and the skills and technology available, can lay the foundation for a successful printing job.

Lanie M. Adamson © 1994

Pharmaceutical Swag – The Good Old Days

By **Rebecca J. Anderson, PhD**

Member, AMWA Pacific Southwest Chapter

Among the utility items in my kitchen drawer is a tchotchke that I picked up years ago from an exhibitor at a professional conference. It's a box cutter with a pharmaceutical company's logo printed along the handle. Obviously, that was a ***long*** time ago. You can't pack that sort of thing in your airline luggage any more.

The rationale for distributing logo-labeled freebies is, obviously, to promote the company's products, but the rationale behind this particular tchotchke has always eluded me. What were they thinking? How can you rationalize the connection between any pharmaceutical product and an item that TSA considers a weapon?

Back then, though, drug marketing was the Wild, Wild West. It was an era when tobacco companies could advertise on television (the Marlboro Man; Joe Camel), but drug companies couldn't. So, the bag men (yes, sales reps always carried a bag and most of them were men) lavished doctors and pharmacists—the people who prescribe and dispense drugs—with all sorts of goodies.

Marketers knew that doctors would grab whatever they could get for free: drug samples, junkets to exotic resorts for "educational workshops," and, of course, those loveable fluffy stuffed animals for the kids. Where I worked, the promotional toys were called tchotchkes, the Slavic word for trinket. Others called them swag, an acronym for "something we all get."

By whatever name, tchotchkes were advertising gimmicks and a preferred marketing ploy, especially for drugs. They kept the product logo in constant view, a subliminal stimulus designed to reinforce prescribing habits. Competing with my box cutter was AstraZeneca's Nexium-labeled Swiss army knives—and hand sanitizer (if you cut yourself). There were Zoloft soap dispensers, Abbott laser pointers, purple Gardasil adhesive bandages, and OxyContin beach hats. Allergan distributed black T-shirts adorned with rhinestones that spelled B-O-T-O-X. And everybody handed out logo-labeled ballpoint pens and coffee mugs.

Doctors' offices looked like a NASCAR event. Tongue depressors, medical calipers, and the paper on the exam table were plastered with logos—everything, except the doctor's white coat. The clever folks at Pfizer devised an innovative light switch for their Viagra campaign. The front-facing silhouette of a man was painted on the face plate, with the toggle switch strategically protruding through the hole, which corresponded to the anatomically correct position of the man's anatomy. The company says this swag was never actually used to promote Viagra—apparently, too much swagger for exam room lights. But prototypes exist.

Then, in 2008, the drug company trinkets vanished, along with Lehman Brothers, Linens 'n Things, and blank VHS tape. The Physician Payments Sunshine Act further restricted drug companies from distributing "items of value" to physicians and





(A beanbag toy shaped like a stomach, advertising Prevacid, an anti-ulcer drug)



teaching hospitals. You might question the tchotchkes' actual "value," but many medical centers took no chances.

A Duluth-based healthcare provider purged all of the logo-emblazoned pens, notepads, coffee mugs, clipboards, mouse pads, and other trinkets—cartloads of them—from its hospitals and clinics. Then, they packed them up and shipped them to Cameroon, where conflict of interest is not an issue. (The drugs advertised on the promotional items aren't available there.)

Massachusetts imposed the toughest restrictions. Doctors from Beantown refused even the complimentary coffee served at medical conferences. (If you ever drank that stuff, you might argue that the boycott had more to do with the brew than who paid for it.)
Some owners cashed in their pharmaceutical gifts on eBay, but most of us still have them stashed in desk drawers, on bookshelves, or—as in my case—in the kitchen drawer. Banished or not, I still use that box cutter.



REBECCA J ANDERSON, PhD, is a freelance medical writer and the author of two books, *Nevirapine and the Quest to End Pediatric AIDS* and *Career Opportunities in Clinical Drug Research*. Prior to medical writing, Dr. Anderson managed research and development projects for twenty-five years in the pharmaceutical/biotech industry. She holds a Ph.D. in pharmacology from Georgetown University. She lives in Southern California, and when she is not writing, she absorbs the sights and sounds of the West Coast's rich culture and heritage. She can be reached at rebeccanderson@msn.com.





(A stuffed toy advertising Mucinex: "Mucinex in, mucus out")





(Bone-shaped paperclips, promoting Actonel, an osteoporosis drug)



AMA-zing Style — the AMA Manual of Style Column

By **Dikran Toroser, PhD, CMPP**, Amgen Inc., Thousand Oaks, Calif.

Open-Access Publication and Scientific Journals

Electronic publishing has become the dominant distribution channel for scholarly journals. In addition, scholars and publishers have conceived new ways—other than charging readers—of collecting the required resources to operate their journals. "Open access" publishing combines these important trends to make articles more widely available. In the open access model, the upfront cost of publishing is borne by the authors or the entity that submitted the publication; in return the work is more widely accessible and has citation advantage.

Open access is the free and unrestricted online availability of content. Strictly applied, open-access publishing means users can freely read, download, copy, distribute, print, search, or link to full text of articles, provided that authors are properly acknowledged and cited.

After much public debate supporting open access to tax-payer funded research, major funding agencies such as the National Institutes of Health (NIH) and the Welcome Trust have started requiring open access publishing from their grantees.[1]

History of Open Access

The open access movement began in the late 1990s following the proliferation of online journals. Declining library budgets, rising numbers of journals (thus the need for more subscriptions), rising subscription prices and the information gap between developed and developing countries were the main drivers of open access.

Types of Open Access Publishing Models

In general, there are 2 main types of open access: self-archiving and open-access publishing.

Self-archiving is the deposition of content in an open archive by the author, sometimes before formal publication, as in ArXiv[2] preprint server maintained by Cornell University. The ArXiv database is primarily used by researchers in the physical sciences, mathematics, and astronomy, but also has a growing collection of preprints in biological and biomedical sciences.

PubMed Central, managed by the National Library of Medicine, archives peer-reviewed articles submitted by the researchers supported by NIH, Welcome, and other agencies requiring open access of their funded research. Many publishers transfer final versions of published articles on behalf of the authors.

Finally, a growing number of institutions have also created archives or institutional repositories. Some examples include the Massachusetts Institute of Technology's DSpace[3] the University of Michigan's DeepBlue,[4] and the University of California's eScholarship Repository[5] are amongst the best-known examples of archiving initiatives. These repositories include published versions of peer-reviewed manuscripts, graduate theses, monographs, eBooks, and other scholarly materials. Interestingly, much of this catalog is crawled by Google and shows up in Google Scholar searches.

A list of open access repositories by country and institutions is available at the OpenDOAR website (http://www.opendoar.org/countrylist.php).

In ***open access publishing***, all or part of a journal is freely open to unrestricted use. The funding model for open-access publishing requires payment from author, institution or other entity, or funding agency. This financial model differs from traditional publishing, in which publication and sustainability of the publishing enterprise are based on subscriptions, advertising, licensing, royalties, reprints, and other forms of revenue.

Although a few journals were published in an open access model before the 1990s, the majority began publication under that model after the year 2000, when the British open access publisher BioMed Central launched a series of open access journals that were peer-reviewed but did not undergo editorial revision and editing. In 2003, the Public Library of Science (PLoS) launched its first in a series of open access journals with an initial $9 million grant from the Moore Foundation. The PLoS journals are peer-reviewed and do provide editorial revision and editing.

Benefits and Challenges of Open Access Publishing

Supporters of complete open access publishing cite the benefits of widespread dissemination of research: universal access, enhanced global collaboration, improved visibility of researchers' work, and the belief that open-access articles will be cited more frequently than restricted-access articles.[1] Opponents express concern about the quality of literature published in a system that may favor those who pay, fairness of the author-pays model for researchers with limited funds (eg, those in developing countries) and the risks to the financial stability of journals with business models based on traditional sources of revenue. Another area of concern is the recent appearance of "predatory" open access publishers that charge publication fees without providing the editorial and publishing services associated with legitimate journals (open access or not).

Since funding agencies began requesting or requiring investigators to permit articles from funded research to be posted on publicly accessible archives (such as PubMed Central), negotiations between these agencies and publishers resulted in another form of open access: ***delayed open access***. This model has now been in use by many scientific and biomedical publishers (especially not-for-profit professional societies) for several years; content is made freely available after a defined interval of time, such as 6 months, 1 year, or 2 years. The interval, which may be influenced by the frequency of journal publication, is intended to protect subscription, licensing, advertising, and other traditional forms of journal revenue.

A number of journals are experimenting with additional types of open access. Open access publishing models are evolving, and debate continues over which models might be sustainable in the long term. A combination of models may be the most appropriate for journals seeking to balance the advantages of open access with the financial requirements of sustainable publication and ongoing maintenance of a journal's Web site. In addition, journals are developing and experimenting with different publication licenses in lieu of standard copyright transfers to permit various access and usage rights.

See pages 184-185 in the AMA Manual of Style 10th edition for additional information.

Acknowledgements: Thanks are due to Ajay Malik, PhD, for useful discussions.

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DIKRAN TOROSER, PhD, CMPP, a member of the AMWA Pacific Southwest chapter, is a regular contributor to the *Postscripts* magazine since 2012. He developed the monthly AMAzing Style column which covers topics from the AMA Manual of Style, and has also written on publication-related topics in these pages. Dikran is currently a Senior Medical Writing Manager at Amgen Inc. in Thousand Oaks, California. He earned his PhD in Biochemistry from Newcastle University (UK), and did his post-doctoral training in biochemical genetics at the John Innes Center of the Cambridge Laboratory (Norwich, UK) and in molecular biology with the USDA. Prior to Amgen, Dikran was on the faculty (research) at the School of Pharmacy at the University of Southern California. He can be reached at dtoroser@amgen.com.

A Medical Writer's "Vision" of Ophthalmology: How Medical Writing Supports Ophthalmic Medical Device Development

By **Clarice Chen**, PhD, DABT, AMWA Pacific Southwest Chapter Member

On Saturday, March 21, 2015, members of the Pacific-Southwest chapter participated in a lunch meeting to learn more about how medical writers support the development of ophthalmic medical devices. The venue was Abbot Medical Optics, Inc, in sunny Santa Ana, CA, where the presenter, Denise Sturrock, MPH, works.

Donna Simcoe, chapter President, warmly greeted members as they streamed into Abbot's conference room for introductions and networking over lunch. Carolyn Bates, Clarice Chen, George Kohan, Shula Pollard, Jane Rollins, Denise Sturrock, Donna Simcoe, Susan Vintilla-Friedman, and Cynthia Wilde attended. To a new member segueing to medical writing, like me, the discussion around the lunch table was helpful and thought-provoking. Topics ranged from useful online training resources, upcoming chapter meetings with educational workshops, and ways to quickly gain experience writing medical news, eg, cover medical conferences at the local convention center for trade magazines.

Following the lively discussion at lunch, it was time for the presentation. The title of the talk was, "**Dot Your 'i's' Don't Cross Your Eyes, A Medical Writer's 'Vision' of Ophthalmology**."

Denise started her presentation with an overview of the most prevalent diseases that cause vision impairment and blindness and highlighted medical devices and equipment used for their treatment.

Some of the most common ophthalmic diseases are age-related macular degeneration (ARMD), glaucoma, cataract, diabetic retinopathy, and refractive error. Interestingly, for ARMD and glaucoma, (particularly, open angle glaucoma [OAG]; increased intraocular pressure), intervention with laser surgery is generally only recommended after initial medical therapies (ie, pharmaceuticals) have failed. In contrast, for the cataract (opacity in the crystalline lens), diabetic retinopathy (retinal changes, including neovascularization caused by diabetes), and refractive error (eye shape prevents accurate focus), laser surgery and/or medical devices are often prescribed as first line therapy.

After laying the landscape of ophthalmic diseases, Denise reviewed the main documents medical writers author to support the clinical research in medical device development and regulatory filings by the company. These documents include clinical trial protocols and reports, clinical evidence reports, and clinical trial registry documents. For these documents, she summarized the regulatory guidances (from the FDA or other international regulatory agencies) for medical devices, types of information needed, and electronic interfaces (eg for clinical trial registry) available for submission to the FDA (or their European counterpart).
As an illustration, key points for writing clinical reports were:

- Focus on what the data reveal instead of restating all of the tabular data
- Be concise (but assume the reviewer will be less familiar with the product/data than the Sponsor/Writer)
- Keep information aligned in different documents



Picture by Donna Simcoe



Picture by Donna Simcoe

(when capturing results in multiple documents at the same time), and
- Follow Sponsor's style guidelines (which may deviate from the standard style guides, eg the AMA Style guide).

Registration of clinical trial is another important task where medical writer may help. Denise assured the audience that registering and populating clinical trial information at the ClinicalTrials.gov website was not as intimidating as it looks!

At the end of the presentation, Denise spearheaded discussion on topics for freelance writers to review with the Sponsor prior to starting a project. Topics included identity of the Sponsor's primary contact, access to search engines, databases, and literature, and templates, due dates for various versions of the document, rate (per hour vs per project), and payment schedules. Attempt should be made to summarize these topics in a written contract prior to start of the project. The conversation was animated and all contributed. It certainly was an educational and "eye-opening" Saturday afternoon!

The speaker, Denise Sturrock, MPH, has been working in the medical device industry since 1989, primarily in ophthalmic clinical research. She earned her bachelor's degrees in biology and psychology from UC Irvine, and MPH degree from UCLA. During the first 10 years of her career, she worked for Allergan Medical Optics, starting as a clinical research associate and ending as the manager of medical communications. She worked as a freelance medical writer for many years while raising her family and in 2012 joined Abbott Medical Optics as a Senior Technical Writer where she manages writing projects that span all product lines in support of product registration and regulatory compliance.



CLARICE CHEN, PhD, DABT, is a board-certified regulatory toxicologist with 14 years of experience in pharmaceutical industry (Bristol-Myers Squibb, Amgen, and Allergan). As a toxicology representative to interdisciplinary project teams that develop drugs, she authored nonclinical sections for regulatory and clinical documents, nonclinical study protocol/reports, and scientific presentations. Clarice obtained her PhD in toxicology from the University of Rochester and completed postdoctoral work in molecular endocrinology at the University of Pennsylvania (her alma mater). She plans to leverage her experience in toxicology and pharmaceutical development to medical writing, as she looks forward to building a career in this field. Clarice can be reached at LinkedIn (https://www.linkedin.com/pub/clarice-chen-phd-dabt/5/819/797) or by email at clarice.w.chen@gmail.com.



http://www.amwa.org/events_annual_conference

What's Up(!) . . . at FDA

By Amanda Fisher, PhD

Member, AMWA Pacific Southwest Chapter

In March, the FDA approved the first bio-similar product in the United States. Zarxio™ (Sandoz Inc.) is biosimilar to Neupogen® (Amgen) and is approved for the same indications. It has been approved in Europe since 2009. The FDA also approved an anthrax treatment, Anthrasil™, developed in part by the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority. Anthrasil™ will be manufactured for addition to the U.S. Strategic National Stockpile. Hospira's troubles continued this month with voluntary recalls of Sodium Chloride and Lactated Ringer's Irrigation solutions after issues with contamination. There will be three advisory committee meetings in April to review NDAs by AstraZeneca and The Medicines Company and a BLA by Amgen..

Selected FDA Announcements

Date	Announcement
3-5-15	Hospira Pharmaceuticals issued a voluntary recall of 0.9% Sodium Chloride injection, USP, 250 mL visIV containers due to contamination with free-floating human hair.[1]
3-10-15	The FDA released a draft guidance for industry titled "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products." The guidance establishes procedures for requesting, preparing, scheduling, conducting and documenting formal meetings with the FDA.[2]
3-11-15	Hospira Pharmaceuticals issued a voluntary recall of Lactated Ringer's Irrigation electrolyte solution due to contamination with *Aspergillus kanagawaensis* mold.[3]
3-11-15	On behalf of the FDA, a U.S. district judge placed a permanent injunction on Specialty Compounding LLC of Cedar Park, Texas, for manufacturing injectable calcium gluconate and other drug products that tested positive for bacterial contamination.[4]
3-30-15	The FDA released a draft guidance for industry titled "Development and Submission of Near Infrared Analytical Procedures." The guidance provides assistance in the development and submission of near infrared (NINR) analyses during the manufacture and testing of pharmaceuticals.[5]

Selected FDA Approvals

Drug	Indication	Company
Zarxio™	Neutropenia. [6,7]	Sandoz Inc.
Cresemba®	Invasive aspergillosis or mucormycosis [8]	Astellas Pharma US, Inc.
Unituxin™	Pediatric high-risk neuroblastoma [9]	United Therapeutics
Cholbam®	Bile acid synthesis and peroxisomal disorders[10]	Asklepion
Anthrasil™	Anthrax exposure [11]	Cangene

Advisory Committee Meetings

Date	Committee
4-14-15	Endocrinologic and Metabolic Drugs Advisory Committee - Results of the cardiovascular outcomes trial for NDAs submitted by AstraZeneca[12]
4-15-15	Cardiovascular and Renal Drugs Advisory Committee- NDA submitted by The Medicines Company [13]
4-29-15	Joint Meeting of the Cellular, Tissue and Gene Therapies Advisory Committee and Oncologic Drugs Advisory Committee - Discussion of BLA submitted by Amgen[14]

. . . continued on next page

Conferences, Workshops and Public Meetings

Date	Title
4-16/4-17	Public workshop on Assessment of Neurocognitive Outcomes in Inborn Errors of Metabolism and Advancing the Development of Pediatric Therapeutics: Assessment of Neurocognitive Outcomes, Silver Spring, MD[15]
4-20/4-21	Homeopathic Product Regulation: Evaluating FDA's Regulatory Framework After a Quarter-Century, Silver Spring, MD[16]
4-22/4-23	REdI: Generic Drugs Forum, Silver Spring, MD[17]
4-28	Public Meeting on Chagas Disease Patient-Focused Drug Development, Silver Spring, MD[18]
5-11	Public Meeting on Functional GI Disorders Patient-Focused Drug Development, Silver Spring, MD[19]

WEBLINKS

- For additional information on approvals, including labeling revisions, tentative approvals, efficacy supplements with supporting clinical data, manufacturing changes or additions, or chemistry; new strength, see http://www.fda.gov/NewsEvents/Newsroom/default.htm [Link]
- For additional information on recalls, market withdrawals, and safety alerts, see http://www.fda.gov/Safety/Recalls/default.htm [Link]
- For information on current drug shortages, see http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm [Link]
- For information on drugs to be discontinued, see http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050794.htm [Link]
- For Orange Book drug product list additions or deletions, see http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm [Link]

[1]http://www.fda.gov/Safety/Recalls/ucm436807.htm [Link]
[2]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM437431.pdf [Link]
[3]http://www.fda.gov/Safety/Recalls/ucm437791.htm [Link]
[4]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm437682.htm [Link]
[5]http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM440247.pdf [Link]
[6]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm [Link]
[7]http://www.nytimes.com/2015/03/07/health/fda-approves-zarxio-first-biosimilar-drug.html?_r=0 [Link]
[8]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm437106.htm [Link]
[9]http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/125516Orig1s000ltr.pdf [Link]
[10]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm438572.htm [Link]
[11]http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm439752.htm [Link]
[12]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm436451.htm [Link]
[13]http://www.fda.gov/AdvisoryCommittees/Calendar/ucm436187.htm [Link]
[14]http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/CellularTissueandGeneTherapiesAdvisoryCommittee/ucm433808.htm [Link]
[15]http://www.fda.gov/Drugs/NewsEvents/ucm434954.htm [Link]
[16]http://www.fda.gov/Drugs/NewsEvents/ucm430539.htm [Link]
[17]http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm435895.htm [Link]
[18]http://www.fda.gov/Drugs/NewsEvents/ucm420130.htm [Link]
[19]http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm430885.htm [Link]

AMERICAN MEDICAL WRITERS ASSOCIATION
Pacific Southwest Chapter

2015 AMWA Pac-SW Conference
May 1 – May 2, 2015

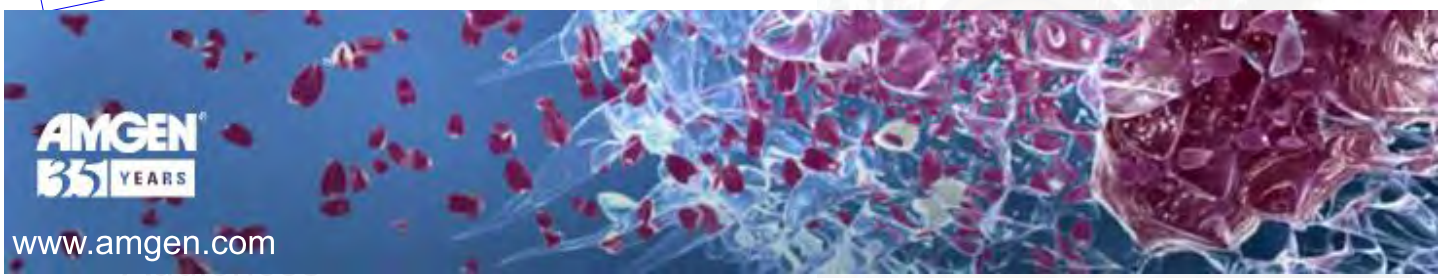
Courtyard Marriott San Diego, Old Town
2435 Jefferson St, San Diego 92

AMWA Pacific Southwest Chapter thanks **Amgen** and **Synchrogenix** for sponsoring the Chapter's Annual conference.

(Look for reports from this conference in the June issue.)

Join us for small
other
old town, home to
ment and cultural venues.

aste of the open sessions:

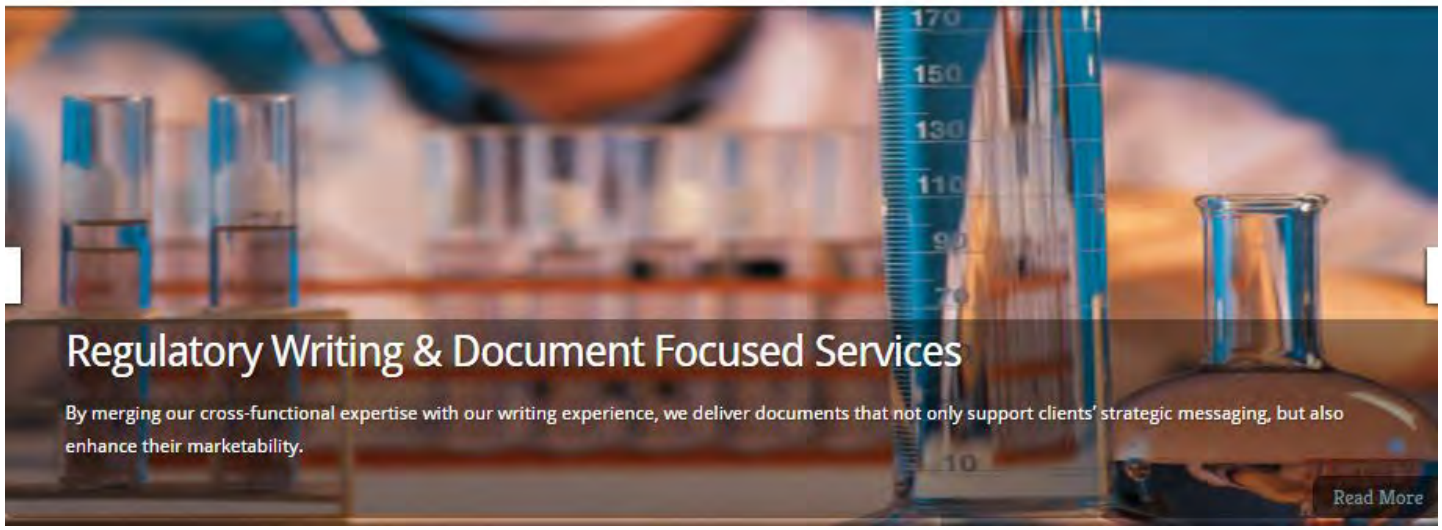


• Medical communications careers (panel discussion)

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AMWA Strategic Planning at the Board of Directors Meeting

Shared By **Noelle Demas, MS**

Past-President, AMWA Pacific Southwest Chapter

April 2015 AMWA Board of Directors' Meeting

As we celebrate 75 years of supporting medical writing excellence, AMWA is focusing on how we can enhance our influence on the profession over the next 75 years.

At the Spring AMWA Board of Directors meeting, Chapter delegates, the Executive Committee, and staff began a strategic planning process that will help determine a clear vision for the organization and shape the mission and goals for the next 3 to 5 years. During the first phase of this planning framework, we explored AMWA in terms of the acronym SOAR:

- Strengths – What do we do well that we can we build on?
- Opportunities – What are our stakeholders asking for?
- Aspirations – What do we care most deeply about?
- Results – How do we know we are succeeding?

During a series of fun, creative, and engaging small-group activities at the meeting, the Board of Directors identified many strengths, opportunities, and aspirations. AMWA's welcoming and diverse community and its broad range of high-quality, educational offerings were among the most frequently noted benefits of AMWA membership.

The next step in the planning process is to seek out volunteers to conduct interviews with additional AMWA stakeholders. These volunteers will work with our strategic planning consultants to identify and interview people who are involved with AMWA at different levels of engagement, including nonmembers and employers of medical communicators. The information gathered from these interviews will be integrated with the ideas generated at the Board of Directors meeting. AMWA leaders will then review all the data to set priorities for AMWA and develop a strategic plan that will capitalize on AMWA's strengths while better meeting the needs of our diverse membership.

If you would like to conduct interviews—or if you would like to be interviewed — please let us know. You can contact either Lori Alexander, Chair of the AMWA Strategic Planning Initiative (lori@editorialrx.com), or Susan Krug, AMWA Executive Director (skrug@amwa.org). We also encourage your feedback and questions on this process, and we look forward to updating you on the process this summer.

Why Go to AMWA's Annual Conference?

By **Kathy Boltz, PhD**,

Member, AMWA Pacific Southwest Chapter

Phew! Early flight today after a night out on Beale Street in Memphis, Tennessee.

My friend summed up why she's been coming to the AMWA Annual Conference: The first year, she came to find out about medical writing and how to do it. The second year, she came to get work as a medical writer. The third year and ever since, she's come to see her friends.

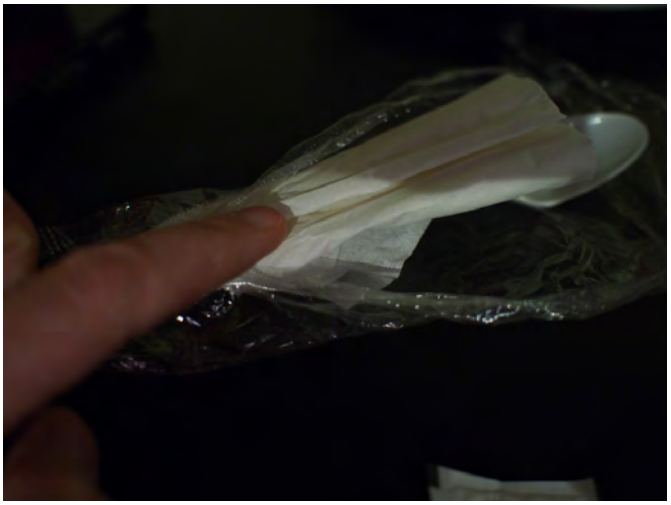
It's always a balance between networking and learning at conference events versus exploring the new city. The AMWA conference is well organized to allow time for networking. Several events at the conference provide food, so you get well fed with your registration fee. It's fun to see friends and to say hi, and to seek out new attendees and hope you can offer advice, just as someone did for you a few years ago.

The chapter networking dinner is a can't miss evening. Our chapter is geographically spread out, and it's great to meet people in person after seeing their names on emails or their voices on phone calls for chapter events. It's also fun to meet AMWA members at various points in their career and to learn about each person's unique career path. We had a group of 45 at our chapter dinner, which was more than we expected when the reservation was made. So, the restaurant ran out of silverware and used plastic silverware, which even came with some ridiculously small napkins, especially for those who got ribs.

I did find time to explore Memphis. First, I always use my phone to locate a walkable coffee shop—hotel coffee is not my favorite. Then, explore public transportation options or befriend a local who arrived in her own car. It was a quick trip down Main Street to attractions like Beale Street and the National Civil Rights Museum.

I recruited a couple friends to explore the Civil Rights Museum with me. The museum was well done and filled with powerful information, imagery, and displays. It was sombering, and we were glad to walk to the Peabody Hotel and watch their ducks afterwards. The Peabody has ducks who live in a penthouse on the roof. Each morning they ride the elevator down to spend their day in the lobby fountain. At 5pm, they march back to the elevator to return to the roof. This was crowded but lighthearted fun.

We had to try a couple establishments on Beale Street to find music that suited us. We ended up at Blues City Café, where we watched a blues jazz group followed by a "honky-tonk" band. My Nashville friend commented afterward that they were more rock-a-billy than honky-tonk; I had to admit that I couldn't distinguish those genres myself. Nevertheless, we all enjoyed their enthusiastic performance. I also learned that, when ordering a beer on Beale Street in a very loud bar, if you don't specify, you get a very large cup of beer.



Tiny silverware and big messy ribs at our chapter dinner.

Social Brunch at Chompies in Arizona

By **Amy Van Gels, DVM**

Member, AMWA Pacific Southwest Chapter

Seven Arizona members of AMWA's Pacific Southwest chapter met on April 11th for a social brunch at Chompie's Deli in Chandler, AZ. The restaurant provided a relaxing environment for networking and socializing with other local medical writers and editors. Attendees included Kathy Boltz, Sharese Terrell Willis, Amy Van Gels, Mary Ann Clifft, Mari Brodersen, and Molly Tomlin. The women chatted about both professional and personal subjects while enjoying large breakfast portions and heaping sandwiches.

Based on the desire of the meeting's attendees, another Arizona event will be scheduled soon. Be on the lookout for more information. To recommend a location, to express interest in attending, to suggest a topic, or to volunteer to speak at a future Arizona event, please contact Amy Van Gels, DVM, at amy@AVGmedical.com or Kathy Boltz, PhD, at kathybphd@gmail.com.



(L to R: Mari, Mary Ann, Amy, Sharese, Molly and Kathy, Picture by Kathy Boltz)

An Evening with Writers and Wine

By **Andrew Hellman**, PhD

Secretary, AMWA Pacific Southwest Chapter

In April, Real Life Sciences and the AMWA Pacific Southwest Chapter co-hosted Writers and Wine, a networking event held in La Jolla, CA. The event was held at We Olive & Wine Bar, which provided a balcony with a view of the sun setting over La Jolla Cove Beach. Over 20 people attended, including recruitment consultants and medical writers with experience ranging from a few days to decades. Everybody enjoyed a variety of delicious wines and hors d'oeuvres until closing time.

The chapter would like to thank Real Life Sciences, a recruiting consultancy and the sponsor of the event, and Recruitment Consultant Conor Trombetta, who initiated and planned the event.





Pictures by Conor Trombetta

Medical Writing Open Positions

Compiled By: **Sharyn Batey, PharmD, MSPH**

Employment Coordinator, AMWA Pacific Southwest Chapter

Medical Science Writer
University of Arizona, Tucson, AZ
http://job-openings.monster.com/monster/bbb086de-4390-429d-88ae-cc0a3620f52b?mescoid=2700440001001&jobPosition=1

Medical Writer
EBSCO, Glendale, CA
http://job-openings.monster.com/monster/aba74a9a-5d3f-4f02-b735-dc11c0451c95?mescoid=2700440001001&jobPosition=4

Medical Writer
Medtronic Inc., Goleta, CA
http://job-openings.monster.com/monster/a69f3c8b-b285-4f96-9417-3c2ca1a0a8bb?mescoid=2700440001001&jobPosition=15

Principal Medical Writer - Device TA
Allergan, Irvine, CA
http://job-openings.monster.com/monster/5aa1cc66-2258-4f1b-8bed-383430902aeb?mescoid=2700440001001&jobPosition=2

Medical Writer - Pharmaceutical
Brandkarma, Irvine, CA
http://job-openings.monster.com/monster/8af005f9-c97d-4303-b0e9-a0ce8b5b4e77?mescoid=2700440001001&jobPosition=5

Medical Writer - Transcatheter Heart Valve
Edwards Lifesciences, Irvine, CA
http://job-openings.monster.com/monster/20210d01-dbc9-4b44-901d-977f5b56ba70?mescoid=2700440001001&jobPosition=1

Clinical Medical Writer
Undisclosed Company
Recruiter: Integrated Resources Inc, La Jolla, CA
http://www.indeed.com/cmp/Integrated-Resources-Inc/jobs/Clinical-Medical-Writer-184ccf7c377aae25

Medical Writer
Undisclosed Company
Recruiter: Klein Management Systems, La Jolla, CA
http://jobs.kleinmgmt.com/candidates/myjobs/openjob_outside.jsp?a=r2jdnwxy4rru6r7ndz0j4g5hns2oti01af0rooatp1vgd27jed5lcowzcpa358jm&from=COMP&id=6660360&SearchString=&StatesString=&jobseq=144&rowsperpage=30&divisions=&divisions2=

Clinical Medical Writer
Undisclosed Company
Recruiter: Eclaro, Los Angeles, CA
http://www.indeed.com/viewjob?jk=6a12fcf55be51343&q=medical+writing&l=Los+Angeles,+CA&tk=19jas6lb05u8jbia

Medical Writer
Quest Diagnostics Incorporated, San Clemente, CA
http://job-openings.monster.com/monster/20afd50c-2816-4153-b87c-2bf331b42c11?mescoid=2700440001001&jobPosition=1

Senior Medical Writer/Medical Writer
Undisclosed Company
Recruiter: BioPhase Solutions, San Diego, CA
http://job-openings.monster.com/monster/b0885244-4d82-4051-ae01-7276623eb3a4?mescoid=2700440001001&jobPosition=2

Senior Manager, Medical Communications
Intercept Pharmaceuticals, San Diego, CA
http://interceptpharma.submit4jobs.com/index.cfm?fuseaction=85416.viewjobdetail&CID=85416&JID=190309&source=Indeed

Medical Writer (Orthopedic Spine Devices and Related Areas)
Nuvasive, San Diego, CA
http://job-openings.monster.com/monster/e6d03020-00ac-4556-92a2-cfac1fb99a72?mescoid=2700440001001&jobPosition=2

Medical Writing Associate Director
Receptos, San Diego, CA
http://www.biospace.com/jobs/job-listing/medical-writing-associate-director-343340

Medical Writer (Long-term Contract)
Undisclosed Company (Southern CA)
Recruiter: Paul Carpenter, Oxford Corp.
paul_carpenter@oxfordcorp.com

Regulatory Writing Senior Manager
Amgen, Thousand Oaks, CA or remote site
http://careers.amgen.com/en/jobs/descriptions/regulatory-writing-sr-mgr-thousand-oaks-job-5062982

If you want to share job leads with the members of the Pacific Southwest Chapter, please contact Sharyn at employment-coordinator@amwa-pacsw.org.

We are in the process of updating the jobs mailing list of chapter members who receive information about open medical writing positions during the month. If you want to either continue receiving the updates or to begin receiving the updates, please contact Sharyn at employment-coordinator@amwa-pacsw.org.

Upcoming Chapter Events

September 19, 2015 - Chapter organized symposium: "Medical Writers' Toolbox Decoded". Location: Thousand Oaks, CA (Amgen) -- SAVE THE DATE



2015 AMWA Salary Survey Now Open!

For the past 26 years, AMWA's salary surveys have served as the most dependable sources of information for employers of medical communicators to set salary ranges and for employees and freelances/independent contractors to negotiate salaries and fees.

https://www.surveymonkey.com/s/amwasalary2015

AMERICAN MEDICAL WRITERS ASSOCIATION

Postscripts

Newsletter of the Pacific Southwest Chapter

Volume 22, Issue 1 January 1994

A FACT-FINDING TOUR OF THE PRINTING INDUSTRY
Saturday, January 22, 1994

9:45 am	**PHOENIX PRESS**, Main and Jamboree, Irvine Exit the 405 Freeway at Jamboree, one block east to Main. Meet in the parking lot. Tour starts promptly at 10 am.
11:30 - 12:45	Lunch at El Torito Grill, 1910 Main Street, Irvine. Main Street near MacArthur, two blocks from Phoenix Press.
1:00 - 2:00	**DIGITAL QUICKCOLOR**, 30-B Maunchly, Irvine 405 Freeway south to Irvine Center Drive. Left on Irvine Center Drive, right on Alton, left on Technology, right on Maunchly, second driveway on left.
Cost	$20, includes lunch (preselected menu items)

Our Words into Print - The Future is Ours

The publishing industry is in the midst of an electronic revolution that took hold about four or five years ago and shows no signs of slowing. We have a rare opportunity to take a behind-the-scenes look at the publishing industry in transition. The idea for this tour came from a course I taught at the national conference in Atlanta last October. The course sold out quickly and was very well received.

Cutting edge technology used in an environmentally sound manner is a challenge met by **PHOENIX PRESS,** a full-service printer with layout, design, scanning, electronic production, full color printing, and binding. See prepress production, high-tech high-speed printing, and learn about vegetable-based inks, the uses of recycled paper in quality printing, and the printing industry of the future.

One of the driving forces in the publishing industry is the need for short-run, fast turn-around, high-impact color printing. **DIGITAL QUICKCOLOR**, the research and development arm of **SIR SPEEDY**, is a showcase for vendors for the Heidelberg GTO-DI four-color printing process with direct-to-press digital imaging. The file goes from the Macintosh or Windows to the printing press, with no

RESERVATION DEADLINE: January 20, 1994

Make your check for $20 payable to AMWA and mail it with this form to: **Ken Faust,**

LONDON,

Printed by *T. P.* and are to be sold by *Mathew Law*, dwelling in *Paules* Church-yard, at the Signe of the *Foxe*, neere *S. Austines* gate. 1622.

Background image via Wikipedia
William Shakespeare - The Historie of Henry the Fourth (1622)
http://commons.wikimedia.org/wiki/File:1H4_Q6_TP_1622.jpg